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| 10/509,686 | 10/12/2004 | Romain Vives | 259880US0X PCT | 3888 |
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| | | | EXAMINER CORDERO GARCIA, MARCELA M | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

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|------------------------------|---------------------------------------|------------------------------|--|
| Office Action Summary | Application No. 10/509,686 | Applicant(s) VIVES ET AL. | |
| | Examiner Marcela M. Cordero Garcia | Art Unit 1654 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-25 is/are pending in the application.
- 4a) Of the above claim(s) 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-20 and 22-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>01/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 19-25 are pending in the application.

Election/Restrictions

Applicant's election with traverse of the species comprising: (1) polyanion = heparin, (2) a dp of 12 and (3) CD4 sequence: SEQ ID NO:13 wherein Xaa1 represents a thiopropionic acid and Xaa23 represents a bi-phenylalanine. Claims 19-20 and 22-25 are readable on the elected species. The election was made in the reply filed on 10/11/2007. The traversal is on the ground(s) that no adequate reasons and/or examples have been provided to support a conclusion of patentable distinctiveness between the identified species. Also, the MPEP at 803 states as follows:

"If the search and examination of an entire application can be made without a serious burden, the Examiner must examine it on its merits, even though it includes claims to distinct or independent inventions."

Applicant's arguments have been carefully considered but not deemed persuasive because the invention is drawn to many materially different CD4 sequences (e.g., SEQ ID NOs: 1-18) and many other encompassed by the broad claim 19. Additionally, the claims are also drawn to materially different polyanions encompassing: heparin, heparan sulphate, a polyanion equivalent to heparin and a polyanion equivalent to heparan sulphate, with various polymerization degrees (10-24). The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of one

species would not necessarily anticipate or even make obvious another species.

Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application.

Because these inventions are distinct for the reasons given above and the search required for each species is not necessarily required for the other species, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement, to be complete, must include an election of the invention to be examined even though the requirement be traversed.

The requirement is still deemed proper and is therefore made FINAL.

Claims 19-20 and 22-25 are presented for examination as they read upon a composition comprising heparin with a dp of 12 and a CD4 peptide of SEQ ID NO:13. Claim 21 is withdrawn as not drawn to the elected species.

Specification

Sequence Compliance

Applicant is advised that the application is not in compliance with 37 CFR §§ 1.821-1.825.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the

sequence rules (37 CFR §§ 1.821- 1.825) in order to completely respond to this office action.

Specifically, no sequence listing / CRF have been provided which includes the amino acid sequences presented e.g., in claim 1, lines 6-7; page 9, lines 8-10, which comprise, e.g., the pentapeptide of broad formula $\text{Asn-Xaa}^{\text{J}}\text{-Cys-Thr}$ or $\text{Ala-Cys-Xaa}^{\text{K}}\text{-NH}_2$, wherein Xaa^{J} represents β -naphthylalanine or phenylalanine or biphenylalanine and Xaa^{K} represents Gly, Val or Ile. In order to satisfy the sequence rules requirements, Applicant needs to provide an amendment to the instant claims and specification to include reference to the appropriate "SEQ ID NO:".

In case of any new sequences not properly identified in the instant specification, Applicant is required to provide a substitute computer readable form (CRF) copy of a "Sequence Listing" which includes all of the sequences that are present in the instant application and encompassed by these rules, a new or substitute paper copy of that "Sequence Listing", an amendment directing the entry of that paper copy into the specification, and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. § 1.821(e) or 1.821(f) or 1.821(g) or 1.825(d). The instant specification will also need to be amended so that it complies with 37 C.F.R. § 1.821(d) which requires a reference to a particular sequence identifier (SEQ ID NO:) be made in the specification and claims wherever a reference is made to that sequence. For rules interpretation Applicant may call (571) 272-2533. See M.P.E.P. 2422.04.

Please direct all replies to the United States Patent and Trademark Office via one (1) of the following:

1. Electronically submitted through EFS-Bio
(<http://www.uspto.gov/ebs/efs/downloads/documents.htm>), EFS Submission User Manual - ePave)
2. US Postal Service:
Commissioner for Patents
PO Box 22313-1450
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3. Hand carry, Federal Express, United Parcel Service, or other delivery service:
U.S. Patent and Trademark Office
Mail Stop Sequence
Customer Window, Randolph Building
401 Dulany Street
Alexandria, VA 22314

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-20 and 22-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him.

The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines,

Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP 2163.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In Regents of the University of California v. Eli Lilly & Co., the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials. Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606; In re Smythe, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . ."). Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. The MPEP does state that for generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative, the Courts have indicated what do not constitute a representative number species to adequately describe a broad generic. In Gostelli, the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. In re Gostelli, 872 F.2d at 1012, 10 USPQ2d at 1618.

In the instant case, the claims are drawn to a composition comprising: a polyanion selected from the group consisting of heparin, heparan sulphate, a polyanion equivalent to heparin and a polyanion equivalent to heparan sulphate, said polyanion having a degree of polymerization dp of 10 to 24, and

A CD4 peptide of sequence (I) below:

Cys or TPA-P¹-Cys-P²-Cys-P³-Cys-Ala or Gln-Gly or (D)Asp or Ser-Ser or His or Asn-Xaa^j-Cys-Thr or Ala-Cys-Xaa^k-NH₂ wherein TPA represents thiopropionic acid, Xaa^j represents β -naphthylalanine, phenylalanine or biphenylalanine, Xaa^k represents Gly, Val or Ile, P¹ represents 3 to 6 amino acids, P² represents 2 to 4 amino acids and P³ represents 6 to 10 amino acids, the amino acids in P¹, P² and P³ being natural or unnatural, identical or different, and P¹, P² and P³ optionally having a common sequence, said peptide having a β -hairpin conformation

wherein the β -turn comprises the amino acid residues Ala or Gln-Gly or DAsp or Ser-Ser or His or Asn-Xaa of its sequence (A). In regards to the “polyanion equivalent to heparin” and “polyanion equivalent to heparan sulphate” terms, these are very broad generic statements for which examples and/or guidance are not presented in the disclosure. By the same token, the CD4 peptides of broad formula (I) are not drawn to a core structure, but rather, to a variable length sequence comprising many different amino acid variations, both natural or unnatural and are exemplified with SEQ ID NOs: 3-18 (please note that SEQ ID NOs: 1-2 are not encompassed by claim 19). The specification does provide examples of what qualify as compounds of the claimed invention, however, these are limited to a few examples such as: Example 1: drawn to synthesis of CD4 peptides (SEQ ID NOs: 1-18); Example 2: drawn to synthesis of heparin and/or heparin sulphate; Example 3: conjugating a peptide of Example 1 with a heparin or heparin sulphate of Example 2. Examples 4-10: testing the compositions (see also Figures 1-12). As stated earlier, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable claim 19 is a broad generic with respect all possible compounds encompassed by the claims. It must not be forgotten that the MPEP states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is “not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.” MPEP 2163. Here, though the claims may recite some functional and structural characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond compounds disclosed in the examples in the specification. Moreover, the specification lack sufficient variety of species to reflect this variance in the

genus since the specification does not provide sufficient examples to exemplify the broad genus claimed by the compositions comprising CD4 peptides of broad formula I and polyanions such as those that are 'equivalent to heparin or heparan sulphate'. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-20 and 22-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 is vague and indefinite by the phrase Asn-Xaa¹-Cys-Thr or Ala-Cys-Xaa^k-NH². This appears to be drawn to a pentapeptide, but it could also be drawn to a tetrapeptide Asn-Xaa^j-Cys-Thr and a tripeptide Ala-Cys-Xaa^k-NH². Appropriate clarification is required. Claim 19 is also deemed vague and indefinite by the phrase: -- of its sequence (A)—at the end of the claim. It appears that Applicant refers rather to

sequence (I). Additionally, claim 19 is also vague and indefinite by the phrase: --
polyanion equivalent to heparin— and --polyanion equivalent to heparin sulphate--. The
metes and bounds for such equivalents are not well delineated, as no definition is
presented that provides guidance with regards to what 'polyanion equivalent' means.

All other claims that depend directly or indirectly from rejected claims and are,
therefore, also rejected under USC 112, second paragraph for the reasons set forth
above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all
obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of
the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of
the various claims was commonly owned at the time any inventions covered therein
were made absent any evidence to the contrary. Applicant is advised of the obligation
under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was
not commonly owned at the time a later invention was made in order for the examiner to
consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g)
prior art under 35 U.S.C. 103(a).

Claims 19-20 and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harrop et al. (AIDS, 1994, citation AK in the IDS of 01/05) in view of Vita et al. (US 2006 0121538).

Harrop et al. teach a composition comprising: heparin and a CD4 peptide. Harrop et al. teach heparin and low molecular weight heparin (enoxaparin) in the compositions (e.g., page 186, column 1, lines 39-44; page 191, column 2, last 3 lines; Figures 1-2 and 6, abstract). Harrop et al. teaches various concentrations of CD4 and heparin (e.g., Figures 1-2 and 6).

Harrop et al. do not expressly teach the specific CD4 peptide of SEQ ID NO: 13, a dp of 12, or a composition comprising 1-10 moles of polyanion per 0.5 to 1.5 mol of the CD4 peptide.

<http://redpoll.pharmacy.ualberta.ca/drugbank/cgi-bin/getCard.cgi?CARD=APRD00068.txt>

teaches that enoxaparin has a molecular weight of 4500 and a dimer molecular weight of about 558 (1116/2), which is equivalent to a dp of $4500/558 = 8$.

Akzo (EP 0 355 905) teaches that heparin fragments and fractions are oligomers or polymers of repeating units consisting of the disaccharides α -D-(1-4)-glucosamine- β -D-(1-4)-glucuronic acid and/or α -D-(1-4)-glucosamine- α -L-(1-4)-iduronic acid (page 2, lines 43-48) and that it has been found that smaller heparin fragments retain an appreciable activity as an inhibitor for HIV replication. At low doses they display a strong activity against HIV-1 as well as against HIV-2 and with respect to HIV-2 they are much more active than standard heparin. It is found that all sorts of heparin fragments display this anti-HIV activity, independently of molecular weight and method of degradation

(see, page 2, lines 14-20). Heparin fragments of molecular weight 6420 (e.g., Example 1) and 4800, 4400, 3900, 3500 (e.g., Example 3) are taught by Akzo. Heparin fragments of molecular weight 6420, the dp is $6420/558 = 11.5$ read upon a dp of 12.

Vita et al. teach a CD4 peptide of sequence (I) below [corresponding to SEQ ID NO:13]: TPA-P¹-Cys-P²-Cys-P³-Asn-Xaa^J-Cys-Ala-Cys-Xaa^K-NH₂ wherein TPA represents β -naphthylalanine or biphenylalanine, Xaa^K represents Val, P¹ represents 4 amino acids, P² represents 3 amino acids and P³ represents 8 amino acids, the amino acids in P¹, P² and P³ being natural or unnatural, identical or different, and P¹, P² and P³ optionally having a common sequence (see Figure 7, sequence for CD4M33). The limitation --said peptide having a β -hairpin conformation wherein the β -turn comprises the amino acid residues Asn-Xaa^J of its sequence (A)—necessarily reads upon the peptide structure of Vita et al. (e.g., Figure 7, CD4M33). The peptide of SEQ ID NO: 13 and the generic family of CD4 peptides of formula (I) (e.g., page 3 [0020]). These peptides have high affinity for the viral protein gp120 (the glycoprotein of the envelope of the immunodeficiency virus which is involved in the first step of replication cycle of the virus) ([0002]), have broad range of action ([0013]) and low antigenicity ([0017]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the composition of Harrop et al. by using the CD4 peptide sequence of Vita et al. The skilled artisan would have been motivated to do so because the CD4 peptides of Vita et al. had high affinity for the viral protein gp120 (the glycoprotein of the envelope of the immunodeficiency virus) which is involved in the first step of replication cycle of the virus [0002], broad range of action [0013] and low

antigenicity ([0017]). There would have been a reasonable expectation of success, given that the peptides of Vital et al. mimicked CD4 behavior [0020]-[0021] and therefore could functionally replace CD4 peptide as taught by Harrop et al. The adjustment of particular conventional working conditions (e.g., using dp 12 heparin instead of dp 8 heparin, optimizing the molar ratio of heparin to CD4 peptide) is deemed merely a matter of judicious selection and routine optimization that is well within the purview of the skilled artisan and because Akzo teaches that the oligomers such as those having 12 dimers (Example 1, see calculations above) still retain anti-HIV activity and have less side effects (page 2, lines 18-24). As such, it would have been obvious to one skilled in the art at the time of invention to determine all optimum and operable conditions (e.g., degree of polymerization as taught by Akzo and CD4/heparin concentration ranges as taught by Harrop et al.), because such conditions are art-recognized result-effective variables that are routinely determined and optimized in the art through routine experimentation ("[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). See MPEP 2145.05). One would have been motivated to determine all optimum and operable conditions in order to achieve the highest yield of the highest purity product in the most efficient manner. One would have had a reasonable expectation for success because such modifications are routinely determined and optimized in the art through routine experimentation.

From the teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcela M. Cordero Garcia whose telephone number is (571) 272-2939. The examiner can normally be reached on M-Th 7:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Marcela M Cordero Garcia
Patent Examiner
Art Unit 1654

MMCG 01/08

